**ENERGY AND ENVIRONMENTAL CABINET**
**Department of Environmental Protection**
**Division of Water**
**(Amendment)**

**401 KAR 8:700. Bottled water.**

RELATES TO: KRS 224.10-100, 224.10-110, 21 C.F.R. 129.35, 165.110

STATUTORY AUTHORITY: KRS 224.10-100, 224.10-110[~~, 21 C.F.R. 165.110~~]

NECESSITY, FUNCTION, AND CONFORMITY: KRS 224.10-110 requires[~~directs~~] the cabinet to enforce the administrative regulations adopted by the secretary for the regulation and control of the purification of water for public and semipublic use. This administrative regulation establishes[~~The purpose of this administrative regulation is to set out~~] provisions to assure the purity of water[~~,~~] placed in bottles[~~,~~] that will be resold as a food for human consumption or other consumer use. U.S. EPA does not have a[~~The U.S. Environmental Protection Agency has no~~] federal regulation relating to bottled water. Certain provisions of this administrative regulation are more stringent than the FDA requirements. The cabinet requires that plans, reports, and monitoring results be submitted to the cabinet to ensure that compliance with all public health standards is achieved without more frequent, costly on-site inspections, and that systems monitor for chlorite more frequently to ensure that public health standards are met for any disinfectant residuals.

Section 1. Applicability. A bottled water system that bottles water within the Commonwealth shall comply with the provisions of 401 KAR Chapter 8 except:

(1)(a) Distribution system monitoring and compliance applicable to public water systems, including provisions for chlorine residual and disinfection by-products; and

(b) The public notification requirements of 401 KAR 8:070 and the reporting requirements of 401 KAR 8:075; and

(2) Water bottled outside the Commonwealth shall not be subject to this administrative regulation regardless of its source.

Section 2. Disinfection and Treatment. (1) Disinfection shall be by chlorination, ultraviolet light, ozonation, or chlorine dioxide.

(2) "Filtration", as defined by 40 C.F.R 141.2, shall be used for all sources identified as "surface water" or "groundwater under the direct influence of surface water", as defined by 40 C.F.R. 141.2.

(3) A bottled water system that uses a surface water source may use treatment techniques that are different from other surface water users if equivalent treatment is provided.

(4) Water located in the line after bottling operations cease shall be flushed before bottling is resumed.

Section 3. Sampling, Monitoring, and Reporting. (1) Analysis shall be performed with a method established in 401 KAR Chapter 8 in a laboratory that shall be certified to conduct testing pursuant to 401 KAR 8:040.

(2) Monitoring results, including the Monthly Operating Report, shall be received by the cabinet no later than the tenth day of the month following the end of the reporting period.

(3) If no treatment or bottling of water occurred during the reporting month, the bottled water system shall notify the cabinet in its Monthly Operating Report established in 401 KAR 8:020, Section 2(7), no later than the tenth day of the following month.

(4) Microbiological Sampling and Monitoring. A bottled water system shall conduct microbiological sampling and testing as established in 401 KAR 8:200.

(a) Each sample shall be taken after water disinfection and prior to the water being placed in a bottle, with no intervening stagnant storage; or

(b) A sample may be taken from a bottle immediately after bottling and before the bottle leaves the plant.

(5) Turbidity Sampling and Monitoring.

(a) A bottled water system shall conduct turbidity sampling once every four (4) hours the system is in operation, regardless of source. The system may substitute continuous monitoring for grab sampling as established in 401 KAR 8:150, Section 3(2), and may use the

average turbidity value for each four (4) hour increment to determine compliance with turbidity performance criterion in paragraph (b) of this subsection.

(b) The turbidity level of the system's product water shall be less than or equal to three-tenths (0.3) nephelometric turbidity units (NTU) in not less than ninety-five (95) percent of the measurements taken each month, and shall never exceed one (1) NTU.

(6) Disinfectant Sampling and Monitoring. Monitoring for disinfectants shall occur after disinfection but prior to bottling, with no intervening stagnant storage.

(a) Chlorine dioxide. A bottled water system that uses chlorine dioxide shall monitor daily for chlorine dioxide.

1. The Maximum Residual Disinfection Level (MRDL) for chlorine dioxide shall not exceed 0.8 mg/L.

2. No two (2) consecutive daily samples shall exceed the MRDL for chlorine dioxide.

3. A bottled water system shall immediately take steps to lower the level of chlorine dioxide in finished water if the MRDL for chlorine dioxide is exceeded.

(b) Chlorite. A bottled water system that uses chlorine dioxide as a disinfectant shall monitor for chlorite annually. The Maximum Residual Disinfection Level (MRDL) for chlorite shall not exceed 1.0 mg/L.

(c)1. Ozone. A bottled water system that uses ozone shall monitor:

a. Monthly for bromate; or

b. Annually for bromate if the system demonstrates that the average bromate concentration is less than 0.0025 mg/L calculated as a running annual average of monthly bromate samples.

2. The Maximum Contaminant Level (MCL) for bromate shall not exceed 0.010 mg/L.

(7) Chemical contaminants.

(a) A bottled water system shall monitor for chemical contaminants after treatment but before bottling, with no intervening stagnant storage.

(b) A sample may be taken from a bottle immediately after bottling and before the bottle leaves the plant.

(c) A bottled water system shall monitor for chemical contaminants:

1. Annually for inorganic and organic contaminants established in 401 KAR 8:250, including sodium;

2. Annually for secondary contaminants established in 401 KAR 8:600, except that a bottled water system may exceed maximum secondary contaminant levels for purposes of bottling mineral water or other water if:

a. Each consumer is informed by labeling as established in 902 KAR 45:050; and

b. The system obtains written cabinet approval after:

(i) Submitting secondary contaminant results before and after treatment; and

(ii) Providing justification for any exceedances;

3. Annually for lead and copper as established in 401 KAR 8:300;

4. Annually for total trihalomethanes and haloacetic acids established in 401 KAR 8:510; and

5. Every four (4) years for radiological contaminants established in 401 KAR 8:550.

(d) Exception. A bottled water system that uses as its source a public water system as defined in 40 C.F.R. 141.2 and is subject to 401 KAR Chapter 8 may substitute the monitoring results of the public water system to satisfy the requirements of this subsection if the bottled water system submits a letter to the cabinet postmarked no later than January 30 of each year stating that it shall:

1. Use the annual results of their public water system source for that calendar year; and

2. Conduct monitoring established in this subsection that has not been conducted by the public water system source.

Section 4. Failure to Comply. (1) A bottled water system that exceeds a MCL or MRDL or otherwise fails to comply with this administrative regulation shall:

(a) Immediately cease operations;

(b) Notify the cabinet as established by 401 KAR 8:020, Section 2(7)(c), and the Cabinet for Health and Family Services, Department

for Public Health; and

(c) Not resume operations without the written approval of the cabinet and the Cabinet for Health and Family Services, Department for Public Health.

(2) Enforcement of this administrative regulation shall be pursued for bottled water systems in the same manner as other public water systems[~~A bottled water system shall comply with the provisions of 401 KAR Chapter 8 with the following exceptions and provisions:~~

~~(1) Distribution systems and free chlorine.~~

~~(a) Administrative regulations pertaining to distribution systems of a public water system, including provisions for a free chlorine residual, shall not apply.~~

~~(b) The requirements of 401 KAR 8:160 and 401 KAR 8:510 shall not apply to a bottled water system, unless specifically included in subsections 5 and 6 of this section~~

~~(2) Microbiological sampling. A bottled water system shall conduct microbiological sampling and testing at least once a week. Tests shall otherwise conform to 401 KAR 8:200.~~

~~(3) Samples location.~~

~~(a) Except as provided in paragraph (b) of this subsection, samples shall be taken after the disinfection of the water and prior to the water being placed in the bottle, with no intervening stagnant storage.~~

~~(b) A sample may be taken from a bottle immediately after bottling and before the bottle leaves the plant, if all other sampling procedures are met.~~

~~(c) Water located in the line after bottling operations cease shall be flushed before bottling is resumed.~~

~~(4) Turbidity sampling. For a bottled water system, regardless of source, turbidity sampling shall be conducted once every four (4) hours the system is in operation. The system may substitute continuous monitoring for grab sampling, with cabinet approval, and may use the turbidity value for every four (4) hours to determine compliance with the turbidity performance criterion. The turbidity level of the system's product water shall be less than or equal to three-tenths (0.3) nephelometric turbidity units NTU, in at least ninety-five (95) percent of the measurements taken each month, and shall never exceed one (1) NTU.~~

~~(5) Sampling, MCL, and MRDL for other contaminants.~~

~~(a) MCLs.~~

~~1. Except for lead and copper, the MCL for a contaminant for which testing is required in this subsection shall be as specified in 401 KAR 8:250, 401 KAR 8:400, 401 KAR 8:420, and 401 KAR 8:510.~~

~~2. Lead and copper. The MCL shall be:~~

~~a. Lead: 0.005 mg/L; and~~

~~b. Copper: one and zero-tenths (1.0) mg/L.~~

~~3. Within twenty-four (24) hours of receiving the test results, a bottled water system shall report to the cabinet violations of the MCL for chlorite and bromate and shall immediately stop bottling operations if violations exist.~~

~~(b) MRDLs.~~

~~1. Except as provided in subparagraph 2 of this paragraph, the MRDL for disinfectants shall be as specified in 401 KAR 8:510.~~

~~2. The MRDL for chlorine dioxide shall be as specified in 401 KAR 8:510, Section 3. No two (2) consecutive daily samples shall exceed the MRDL, monitored at the treatment plant after treatment.~~

~~3. A bottled water system shall report to the cabinet a violation of the MRDL for chlorine dioxide as soon as possible after learning of the exceedance, and shall immediately take steps to lower the level of chlorine dioxide in the system.~~

~~(c) Sampling.~~

~~1. A bottled water system shall monitor annually for the following:~~

~~a.(i) Contaminants specified in 401 KAR 8:250, 401 KAR 8:400, and 401 KAR 8:420, except as provided in subclause (ii) of this clause.~~

~~(ii) A bottled water system that uses as its source a public water system subject to 401 KAR Chapter 8 may, with written approval from the cabinet, substitute the monitoring results of the public water system for the monitoring required by clause a of this subparagraph. The bottled water system shall submit a letter by January 30 of each year, stating that it shall use the annual results of their purchasing~~

~~system. The system shall include the PWSID of the purchasing system.~~

~~b. Lead;~~

~~c. Copper;~~

~~d. Total trihalomethanes, or TTHMs; and~~

~~e. Haloacetic acids, or HAAs;~~

~~2. A bottled water system shall monitor for radionuclides annually, according to the procedures in 401 KAR 8:550.~~

~~(6) Disinfection.~~

~~(a) Disinfection shall be by chlorination, ultraviolet light, ozonation, chlorine dioxide, or other method approved by the cabinet that provides equivalent treatment.~~

~~(b) A bottled water system that uses:~~

~~1. Chlorine dioxide shall monitor for chlorite daily in the treatment plant; or~~

~~2. a. Ozone shall monitor monthly for bromate in the treatment plant; or~~

~~b. Alternatively, a system that uses ozone shall monitor annually for bromate in the treatment plant, if the system demonstrates that the average bromide concentration is less than 0.05 mg/L, calculated as a running annual average of monthly bromide samples.~~

~~(7) Surface water treatment. Bottled water systems using surface water sources may, with cabinet approval, use treatment techniques that are different from other surface water users, if equivalent treatment is provided.~~

~~(8) Maximum contaminant level exception labeling. With approval of the cabinet, bottled water systems may exceed maximum contaminant levels for secondary contaminants for purposes of bottling "mineral water" or other water, if consumers are informed by proper labeling.~~

~~(9) Water bottled outside Commonwealth. Water bottled outside Kentucky shall not be subject to this administrative regulation, regardless of its source.~~

~~(10)(a) Analyses shall be performed in accordance with methods approved by 401 KAR Chapter 8 or 21 C.F.R. 165.110, in laboratories that are certified to conduct testing pursuant to 401 KAR 8:040.~~

~~(b) Monitoring results shall be received by the cabinet no later than the tenth day of the month following the end of the reporting period.~~

~~(11) The public notification requirements of 401 KAR 8:070 and the reporting requirements of 401 KAR 8:075 shall not apply to a bottled water system.~~

~~Section 2. Failure to Comply. A bottled water system that exceeds a maximum contaminant level or MCL, or a maximum residual disinfectant level or MRDL, or otherwise fails to comply with 401 KAR Chapter 8 shall:~~

~~(1) Immediately cease operations;~~

~~(2) Notify the cabinet and the Cabinet for Health and Family Services, Department for Public Health; and~~

~~(3) Not resume operation without the written approval of the cabinet~~].

LEONARD K. PETERS, Secretary

APPROVED BY AGENCY: July 9, 2014

FILED WITH LRC: July 15, 2014 at 9 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 28, 2014 at 6:00 p.m. Eastern Time at the Department for Environmental Protection, Room 301D, 300 Fair Oaks Lane, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by 5 workdays prior to the hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until the close of business on September 2, 2014. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact

person.

CONTACT PERSON: Carole J. Catalfo, Internal Policy Analyst, Division of Water, 200 Fair Oaks Lane, 4th Floor, Frankfort, Kentucky 40601, phone (502) 564-3410, fax (502) 564-9003.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Peter Goodmann

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes requirements for public water systems that bottle water in Kentucky for sale to consumers.

(b) The necessity of this administrative regulation: KRS 224.10-100(30) and KRS 224.10-110 authorize the cabinet to promulgate administrative regulations for the purification of water for public and semipublic use. 21 C.F.R. 129 establishes FDA standards regarding the sources, testing, and processing of bottled water. Kentucky's definition of public water systems has always included systems in Kentucky which bottle water for purchase and consumption, and are subject to requirements of 40 C.F.R 141 and 401 KAR Chapter 8. This administrative regulation is necessary to establish requirements for public water systems that bottle water in Kentucky for public sale and consumption and to protect public health.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 224.10-100(28) and 224.10-110 authorize the Cabinet to adopt and enforce administrative regulations for the purification of water for public and semipublic use and for the construction and operation of water treatment and distribution systems.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes disinfection, sampling and testing methods and places limits on contaminants in bottled water which are essential to protect public health.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments correct a reference to federal regulation, reorganize the regulation for clarity, and place specific limits on contaminants for bottled water systems.

(b) The necessity of the amendment to this administrative regulation: These amendments are necessary because many of the requirements located in 401 KAR Chapter 8 apply to all public water systems, but not specifically bottled water. Kentucky bottled water systems are considered public water systems subject to requirements of 40 C.F.R 141 and 401 KAR Chapter 8. The amendments will assure consumers that water bottled in Kentucky for purchase and consumption is properly tested and meets the maximum contaminant and residual disinfectant levels that are applicable to bottled water systems.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 224.10-100(28) and 224.10-110 authorize the cabinet to adopt and enforce administrative regulations for the purification of water for public and semipublic use. The amendments clarify treatment, sampling, and testing methods and establish maximum contaminant levels for bottled water to ensure that it meets safety and health standards.

(d) How the amendment will assist in the effective administration of the statutes: This administrative regulation establishes disinfection, sampling and testing methods and places limits on contaminants in bottled water which are essential to protect public health.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation applies to six (6) privately-owned public water systems currently bottling water in Kentucky, and any future bottled water systems.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The substantive requirements of the existing regulations remain unchanged. The amendments clarify disinfec-

tion, sampling and testing requirements, reporting requirements, and places limits on contaminant levels in bottled water.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The costs of complying with this administrative regulation remain largely unchanged.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The amendments provide clear, consistent, and definitive requirements specifically for bottled water systems which will make compliance easier than in the past.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional initial costs to implement the regulation.

(b) On a continuing basis: There are no additional continuing costs to implement this regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation? The source of funding for the bottled water program is a combination of state general funds and federal funds provided to administer the Safe Drinking Water Act.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase in fees will not be necessary. The cabinet has received increased funding from the US Environmental Protection Agency (EPA) to implement new provisions of the Safe Drinking Water Act.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish fees or directly or indirectly increase fees.

(9) TIERING: Is tiering applied? Yes. This administrative is applicable only to bottled water systems, not all public water systems. Bottled water systems may use treatment techniques other than those described in the regulation as long as equivalent treatment is provided. Bottled water Systems may substitute continuous monitoring for grab sampling under certain conditions. Systems may exceed secondary contaminant levels with cabinet approval provided consumers are informed by proper labeling and the system provides certain information to the cabinet. Bottled water systems that use public water systems as a source may substitute the monitoring results of the public water system to satisfy some requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Six (6) public water systems will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 224.10-100(28), 224.10-110, 401 KAR 8:700, 21 C.F.R. 129 and 165.110

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None.

(c) How much will it cost to administer this program for the first year? No additional costs.

(d) How much will it cost to administer this program for subsequent years? No additional costs.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None

Expenditures (+/-): None

Other Explanation: None

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. There is no Safe Water Drinking Act mandate for bottled water systems. 21 C.F.R. 129 and 165.110 establish federal Food and Drug Administration (FDA) standards regarding bottled water. Kentucky's definition of public water systems has always included systems in Kentucky which bottle water for purchase and consumption, and are subject to requirements of 40 C.F.R 141 and 401 KAR Chapter 8.

2. State compliance standards. KRS 224.10-100(28), 224.10-110, 401 KAR 8:700

3. Minimum or uniform standards contained in the federal mandate. 21 C.F.R. 129 establishes FDA standards regarding the sources, sampling, testing, treatment and processing of bottled water.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements than those required by the federal mandate? This regulation requires turbidity sampling and testing consistent with the Safe Water Drinking Act, but otherwise reflects FDA requirements for bottled water. The cabinet requires that plans, reports, and monitoring results be submitted to the cabinet to ensure that compliance with all public health standards is achieved without more frequent, costly on-site inspections, and that bottled water systems monitor for contaminants to ensure that public health standards are met for any disinfectant residuals.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Kentucky bottled water systems are considered public water systems already subject to 40 C.F.R. 141 and 401 KAR 8:010. More frequent turbidity sampling and testing mirrors the Safe Water Drinking Act and assures a cleaner, safer product for consumers.